# PROVIDING PUBLIC HEALTH INFORMATION TO PREVENT SKIN CANCER

Review of effectiveness and cost-effectiveness

Addendum

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# West Midlands Health Technology Assessment Collaboration

The West Midlands Health Technology Assessment Collaboration (WMHTAC) is an organisation involving several universities and academic groups who collaboratively undertake research synthesis to produce health technology assessments. Most of our members are based in the Department of Public Health, Epidemiology & Biostatistics, University of Birmingham, however other members are drawn from a wide field of expertise including economists and mathematical modellers from the Health Economics Facility, University of Birmingham.

WMHTAC produce systematic reviews, health technology assessments and economic evaluations for NHS R&D HTA programme (NCCHTA), the National Institute for Health and Clinical Excellence (NICE), and for the health service in the West Midlands. WMHTAC also undertakes methodological research on research synthesis, and provides training in systematic reviews and health technology assessment.

## Name of other institution(s) involved

WMHTAC work in close collaboration with the Peninsula Technology Appraisal Group

(PenTAG) with respect to providing support to the CPHE.

# **Executive Summary**

The main report lists (in Appendix 15) 26 before and after studies that met the inclusion criteria, but were not analysed. Two of them were misclassified; one was an RCT (Buller 1996) and one was a controlled before and after study (Vitols).

## Methods:

Methods were identical to those in the main report.

Findings: Effectiveness

Theme 1: Verbal advice vs. Current provision of information/ do nothing

Studies on prevention in children

School based studies in children aged seven to 11 years

One American cluster RCT (rated -) was initially misclassified as a before and after study. It investigated the effectiveness of a curriculum in 447 fourth to sixth grade children. *"The "Sunny Days, Healthy Ways" curriculum consisted of five multidisciplinary units"* delivered by trained teachers one each week. Participants were followed-up for up to eight weeks.

The evidence from this study is consistent with evidence from RCTs analysed in the main report. It indicates a significant increase in knowledge and no clear tendency with regard to behaviour changes. Therefore this study does not alter, but concurs with, the conclusions of the main report. (Buller 1996)

#### Theme 7: Head to head comparisons within the same intervention type

#### Verbal advice in children

#### School based studies in children aged eight to 12 years

One Australian cluster controlled before and after study (rated -) was initially misclassified as a before and after study. It compared in 983 children aged eight to 12 years the effectiveness of two formats of teaching: a presentation and a question and answer session. Children were followed-up for two weeks.

Results were presented mainly for both groups together, comparing baseline with follow-up. For the comparison between teaching formats it was only stated, that *"both the formal presentation and the interactive session were effective in increasing knowledge (P<0.0005 for both groups), with no significant differences in the average gain in scores between these two teaching methods."* Given this limitation, this study does not add to the evidence presented in the main report. (Vitols)

# Findings

The main report lists (in Appendix 15) 26 before and after studies that met the inclusion criteria, but were not analysed. Two of them were misclassified; one was an RCT (Buller 1996) and one was a controlled before and after study (Vitols).

Both studies investigated group based verbal advice in children in a school setting. Below, in Table 1 these have been added in red font to the coverage table that was included in the main report.

	Current		Children		Adults
	provision of information/		school (age 4-7)		university/ college
	do nothing	2 RCT	Buller 2006a (rated -)	3 RCT	Jackson (rated ++)
			Loescher (rated +)		Katz (rated -)
		1 CBA	Kidskin (rated +)		Mickler (rated ++)
			<u>school (age 7-11)</u>		hospital/ medical practice
		5 RCT	Buller 1994 (rated -)	1 CBA	Jones 2007 (rated -)
ŗ			Buller 1996 (rated -)		
rat			Buller 1997 (rated -)		
Comparator			Buller 2006a (rated -)		sports venue
lo No			Hornung (rated +)	1 RCT	Parrott (rated -)
U		1 CBA	Hewitt (rated -)		
			<u>School (age 11-16)</u>		
		6 RCT	Buller 2006b (rated +)		
			Girgis (rated -)		
			Hughes (rated -)		
			Kristjánsson (rated +)		
			Mermelstein (rated -)		
			Syson-Nibbs (rated -)		

Table 1 Coverage of analysed studies on verbal advice by comparator, population and setting

	2 CBA Reding (rated -) Rodrigue (rated -)	
	<u>Domicile</u> 1 RCT   Turrisi (rated +)	
	<u>school (age 4-11)</u> 1 CBA Buller 2006a (rated -)	
Verbal	2 CBA Hewitt (rated -) Vitols (rated -)	
advice	school (age 11-16) 1 RCT Hughes (rated -)	
	Community 1 CBA Rodrigue (rated -)	
Mass-media campaigns		1 RCT Mickler (rated ++)
Printed materials	<u>school (age 7-11)</u> 1 CBA Barankin (rated -)	university/ college1 RCTMickler (rated ++)
New media	school (age 7-11)1 RCTHornung (rated +)	
Verbal		hospital/ medical practice
advice + printed materials		1 RCT Clowers-Webb (rated +)

The Buller 1996 RCT falls within the same category as four other RCTs (three by Buller *et al* investigated versions of the same curriculum *"Sunny Days, Healthy Ways"*) and one controlled before and after study. The follow-up in this trial was not longer than in any other RCT in this category. The primary outcomes assessed were knowledge and behaviour change. The results of Buller 1996 indicated a significant increase in knowledge and no clear tendency with regard to behaviour changes – which is consistent with the results of other RCTs in this category. Therefore this study does not alter, but concurs with, the conclusions of the main report.

The other misclassified study (Vitols) does not fall into the same category as other studies analysed in the main report as it is the only study to compare two forms of verbal advice in a school setting delivered to children – approximately in the seven to 11 age category. However, although this study was designed as a controlled before and after study, the results are for the most part not reported for both study arms separately, but combined as in a before and after study. The authors only indicated that in both study arms there was a significant increase in knowledge and that there was no significant difference between the two groups. Given this limitation, this study does not add to the evidence presented in the main report.

Both studies are described in detail below and relevant evidence tables and quality assessment tables are provided.

# Buller 1996<sup>1</sup> - *cluster (school for intervention; class for pre-testing and follow-up) RCT*

This RCT (rated -) was set in Tucson, Arizona, USA. Study year was not reported. Four hundred forty seven children participated in the study: 251 were allocated to the intervention and 196 to the control group.

Age was not reported, but taking into account the characteristics of the American education system it is probably nine to twelve years.<sup>2</sup> There were 49.4% females in the intervention and 48.5% in the control group. Race and/or ethnicity of students in the intervention and control group was: White 65.7% and 61.7%, Black 2.0% and 3.6%, Hispanic 13.1% and 7.7%, Other 15.5% and 15.8%, unknown 3.6% and 11.2%.

This study used a Solomon Four-Group design, which according to the authors *"protects against threats to internal validity, including history, maturation, testing, statistical regression, and instrumentation."* First four schools were randomly allocated: two to intervention and two to control. Next, classes within each pair of schools were randomised to have outcomes pre-assessed or not and outcomes

assessed at either one or eight weeks after completion of the intervention. An illustration of the study design is provided in Figure 1 below.

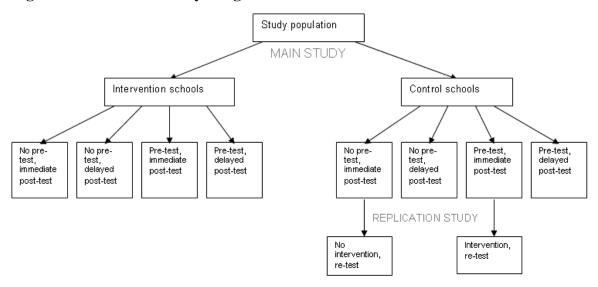


Figure 1 Buller 1996 - study design

The intervention was the "Sunny Days, Healthy Ways" curriculum and it consisted of "five multidisciplinary units and a student workbook that presented material from science, history, social studies, health, and geography in a comprehensive cause-and-consequence presentation about the relationship between human beings and the sun. The units cover properties of the sun, composition of human skin, historic attitudes toward tanning, skin cancer, and strategies to reduce sun exposure in an interactive lesson/activity format. Each unit (about 50 minutes in length) contained lesson material, in-class and takehome activities, a glossary of key terms, a quick review, and a student/parent newsletter.

Health communication experts, dermatologists, teachers, and curriculum consultants collaborated to develop the curriculum. It complements state and national skin cancer prevention information resources (...), although most preexisting programs are aimed at children in kindergarten through third grade. The curriculum also conformed to the disease prevention section of the State of Arizona Board of Education's comprehensive essential skills."

The intervention was delivered by trained teachers over five consecutive weeks, one unit each week.

"Before implementation teachers attended a 3-hour orientation, training, and practice session conducted by the project investigators and staff."

The control group received no curriculum between pre-test and post-test. However one of the control groups was later given the intervention and this group was compared to a re-testing of another control group (see Figure 1). The results of this replication study are not discussed here, but they can be found in Table 3.

The "Sunshine and Your Skin Survey" consisting of 89 items was used to evaluate the effectiveness of this intervention. It tested knowledge using a tenitem term recognition scale and 35 "true/false/don't know" questions on the curriculum content. Correct responses were summed to a knowledge score. Eleven "yes/no" items were used to assess changes in attitudes. Two attitude subscales were identified: favour a tan (three items) and barriers to sunscreen use (two items) with higher scores indicating less sun protective attitudes. Thirteen items ("always/sometimes/never") measured the frequency of children performing sun protective behaviours. Three subscales were identified sunscreen use in summer (two items), lip balm use (two items) and hat use (two items). The remaining items measured "use of protective clothing in summer and winter, sunscreen in winter, sunglasses on sunny days, frequency of lying out in the sun to get a tan, the SPF of sunscreen used, and parts of the body on which sunscreen is applied". Higher scores indicated more frequent use of each behaviour. Parent's frequency of practicing sun protective behaviours was measured by eight items ("always/sometimes/never"). This survey also measured participant characteristics: skin sun sensitivity, ethnicity, sex and years lived in Arizona.

A chroma meter was used to measure skin exposure to UV radiation. Scores were measured on two scales: L\* scale which measures skin lightness (a decrease in score indicates skin darkening) and b\* scale which measures

saturation (an increase in this score indicates skin darkening). "To reduce variation in readings, five measures were made on the underside of each student's upper arm (an unexposed area) and five measures were made on the lower outer side of the same arm (an exposed area). Readings were averaged at each measurement site for analysis."

Apart from being allocated to the intervention or control, groups differed on being pre-tested or no and length of follow-up. Pre-tested groups completed the survey *"just before the implementation of the curriculum". "Baseline skin tanning measurements were performed (…) at the beginning of the intervention in the pretested groups".* 

"The immediate posttest groups completed the (...) survey 1 week after completing the curriculum, in early April. The delayed posttest groups completed the survey 8 weeks after implementation in mid-May. Skin tanning measurements also were obtained for the delayed posttest groups at this time."

#### Results

It was often not entirely clear for which group and follow-up results were being reported. Different numbers of participants were reported for some outcomes. For some items scores for subgroups with and without pre-testing and with different follow-up were provided in addition to the main analysis (it needs to be highlighted that main analyses did not use data from all participants and the numbers were inconsistent with numbers in subgroups). These can be found in Table 3.

#### Primary outcomes

The post-test term recognition score adjusted for baseline was higher in the intervention group (9.52, measured in 102 participants) than in the control group (7.11, measured in 76 participants), p was reported as 0.000. This indicated that

participants in the intervention arm recognised on average more terms from the curriculum than the controls.

Also the knowledge score was higher in the intervention group (28.82, measured in 102 participants) than in the control group (18.72, measured in 75 participants) with p reported as 0.000.

With regard to children's behaviour, it is often difficult to draw any conclusions as no range of possible scores was provided. It was often not clear what a score or a difference in score represents and it was only stated that *"higher scores indicated more frequent use of each behaviour"*. This is however not in accordance with authors discussion of children lying out in the sun to get a tan (higher score appears to indicate less frequent behaviour).

When measurements on the entire behaviour scale were compared, mean scores for behaviour frequencies hardly differed: 1.95 in the intervention group (measured in 102 participants) and 1.93 in the control group (measured in 75 participants), with p=0.512.

There was a significantly higher frequency for only some of the investigated individual behaviours in the intervention group compared to controls. There was no significant difference in unadjusted post-test sunscreen use in summer scores between the intervention (2.25, measured in 232 participants) and control group (2.21, measured in 169 participants), with p=0.592. Sunscreen use in winter score was slightly higher in the intervention (1.39, measured in 99 participants) than in the control group (1.30, measured in 75 participants), but was not statistically significant (p=0.241). Lip balm use was marginally more frequent in the intervention group (1.68, measured in 70 participants), the difference was however not significant with p=0.213.

Hat use score was 1.93 (measured in 102 participants) and 1.90 (measured in 75 participants) respectively, with p=0.673. Wearing protective clothing was also

9

marginally more frequent in the intervention group (1.51, measured in 99 participants) than in the control group (1.44, measured in 72 participants), but the difference was not statistically significant (p=0.425). The mean post-test score for wearing protective clothing in winter was higher in the intervention group (2.02, measured in 239 participants) than in the control group (1.94, measured in 177 participants), but the difference was not statistically significant with p=0.263. Wearing sunglasses on sunny days was marginally more frequent in the intervention group (1.83, measured in 102 participants) than in the control group (measured in 75 participants), the difference was not statistically significant with p=0.521.

The unadjusted score for the SPF of sunscreen used was significantly (p=0.003) higher in the intervention (2.92, measured in 195 participants) than in the control group (2.77, measured in 106 participants). The mean score for the place of applying sunscreen (the authors did not provide a clear definition of this outcome) was marginally lower in the intervention (2.41, measured in 100 participants) than in the control group (2.48, measured in 71 participants), the difference was however not significant with p=0.490.

For some behaviours interpretation is unclear. As mentioned above there is an inconsistency between the description of study methods and discussion of the results. These results can be interpreted both as indicating more and less sun protective behaviour in the intervention group. Such items are reported without comment in Table 2 below.

Table 2	Behaviour	items -	Buller	1996

Outcome	Intervention mean (number of participants)	Control mean (number of participants)	p-value for difference
play outside early or late in the day	1.78 (100 participants)	1.90 (73 participants)	p=0.274
trying not to get sunburned	2.60 (102 participants)	2.72 (74 participants)	p=0.125
lieying out in the sun to get a tan	2.60 (102 participants)	2.49 (73 participants)	p=0.112

The full range of parental behaviours assessed was not clear even though summary scores were given. The summary scores indicated no difference between groups (1.85 in both groups, measured in 102 participants in the intervention and 75 in the control group, p=0.965).

With regard to skin exposure, mean post-test chroma meter L\* scores for the upper arm were 65.65 in the intervention (measured in 58 participants) and 64.94 in the control group (measured in 33 participants) - the difference was statistically significant with p=0.045 and indicated less skin darkening in the intervention group. The trend was similar for lower arm with a mean of 54.49 and 53.11 respectively (measured in the same numbers of participants as upper arm) and the difference was also significant with p=0.009. The difference (not clear between which measurements) was 10.49 in the intervention group (measured in 128 participants) and 11.72 in the control group (measured in 88 participants) and was statistically significant with p=0.003. Although the differences were statistically significant, authors provided no indication of the range of the scale or what difference is clinically meaningful.

Mean post-test chroma meter b\* scores for the upper arm were similar in both study arms: 13.01 in the intervention (measured in 58 participants) and 13.02 in the control group (measured in 33 participants) - the difference was not statistically significant with p=0.975. For lower arm the mean score was 19.56 and 19.25 respectively (measured in the same numbers of participants as upper arm) and the difference was also not significant with p=0.293. The difference (again not clear between which measurements) was -6.64 in the intervention group (measured in 58 participants) and -6.08 in the control group (measured in 33 participants) and statistically significant with p=0.211.

#### Secondary outcomes

With regard to attitudes, participants in the intervention group favoured a tan significantly less than those in the control group. Children in the intervention group also saw significantly less barriers to sunscreen use than the controls.

Two individual parent behaviours were reported in this study: frequency of checking child's skin and knowing what to do if a change is found on the skin. For both outcomes scores were significantly higher in the intervention group.

#### Limitations

Internal validity was rated "-". Full details of quality assessment are reported in Table 4.

The findings are probably applicable only to population or setting included in the study – the success of broader application is uncertain.

The authors highlighted potential limitations due to the validity of children's selfreports of behaviours. There is also the possibility that children did not remember if precautions were taken, as this was often a parent decision. Clustering was not accounted for in the analysis. Only 62% of parents and their children who were invited to participate in the study agreed (slightly lower participation in control group; unclear if participants knew which group they would be allocated to). The authors also stated that adjustment for baseline might limit direct applicability.

Other limitations were identified when conducting this review. Given the time in which the study was conducted, it could not possibly have measured actual behaviours in relation to winter. Providing children in the control group with the intervention (within the replication study) could have possibly caused contamination of the groups with the delayed post-test. The follow-up was relatively short (one week to eight weeks after completion of the intervention). Intention to treat analysis was not undertaken. It was often not clear to which groups and follow-up periods results referred and numbers of participants analysed were inconsistent. No analyses were reported for the entire study sample. The authors report that *"sixteen consenting students who were scheduled to complete both a pretest and a posttest did not complete both tests"*, however for some outcomes it appears that data from more participants was not analysed. For many of the outcomes assessed the method of scoring was

unclear as were the range of possible scores and the relevance of a difference in score.

#### **Evidence statement**

An American cluster RCT (rated -) investigated the effectiveness of a curriculum in 447 fourth to sixth grade children. *"The "Sunny Days, Healthy Ways" curriculum consisted of five multidisciplinary units* [delivered by trained teachers one each weak] and a student workbook that presented material from science, history, social studies, health, and geography in a comprehensive cause-andconsequence presentation about the relationship between human beings and the sun. The units cover properties of the sun, composition of human skin, historic attitudes toward tanning, skin cancer, and strategies to reduce sun exposure in an interactive lesson/activity format. Each unit (about 50 minutes in length) contained lesson material, in-class and take-home activities, a glossary of key terms, a quick review, and a student/parent newsletter." The control group received no curriculum.

This study provided evidence of a significantly higher post-test recognition of curriculum terms (p reported as 0.000) and knowledge score (p reported as 0.000) in the intervention group compared to controls. Both scores were adjusted for baseline.

With regard to children's sun protective behaviour there was no evidence of a difference for the overall score (p=0.512). For only one individual item – SPF of sunscreen used - was there a statistically significant difference (p=0.003) which indicated a more sun-protective behaviour in the intervention arm compared to controls. A positive (however not significant) trend was also observed in the intervention group compared to controls for: lip balm use (p=0.213), wearing protective clothing in summer (p=0.425), wearing protective clothing in winter

(p=0.263), sunscreen use in winter (p=0.241) and wearing sunglasses on sunny days (p=0.521). Similar results were observed in both groups for: sunscreen use in summer (p=0.592) and hat use (p=0.673). For the following behaviours interpretation of the direction of effect was unclear due to reporting issues: play outside early or late in the day (p=0.274), try not to get sunburned (p=0.125), lie out in the sun to get a tan (p=0.112) and place of sunscreen application (p=0.490).

There was no evidence that the scores for parent protective behaviour on their children differed between both groups (p=0.965).

Measurements on chroma meter L\* scale provided evidence of less skin darkening in the intervention group compared to the control group (p=0.045 for upper arm, p=0.009 for lower arm, p=0.003 for difference). There was no significant difference in the b\* score (p=0.975 for upper arm, p=0.293 for lower arm, p=0.211 for difference). These results need to be interpreted with caution, as no information was provided on the range of the scale and what is a clinically meaningful difference.

Results of this study are probably applicable only to population or setting included in the study – the success of broader application is uncertain. (Buller 1996<sup>1</sup>)

<b>Table 3 Eviden</b>	ce table: Buller 1996
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Study details	Population and setting	Method of allocation to intervention/control	Outcomes and methods of analysis	Results	Notes
	setting Source population/s: 39 elementary schools in Tucson Unified School District Country: USA Study year: not reported Eligible population: six schools where: "(1) school enrolment included 70% or more white students because risk for skin cancer is higher in this racial group; (2) the school was not a magnet school; (3) the school had fourth, fifth, and sixth grade classes; and (4) the school had a	intervention/control Method of allocation: "Two schools were randomly assigned to the intervention, and one class from each of the three grade levels from each school was randomly assigned to each of four intervention groups. Likewise, three classes (one class from each of the three grade levels) within each of the two control schools were randomly assigned to each of four control groups." Measures to minimise confounding: Solomon Four-Group design was used, which "protects against threats to internal		Results         Primary outcomes:         MAIN STUDY         Mean post-test scores adjusted for pre-test; unadjusted scores reported where pre-testing was significant in the initial analyses (#)         Knowledge         Term recognition         • 9.52 intervention (102 participants); 7.11 control (76 participants); p reported as 0.000         • Pre-tested – immediate: 9.54 intervention (46 participants); 6.90 control (48 participants); p not reported         • Pre-tested – delayed: 9.64 intervention (59 participants); 6.87 control (31 participants); p not reported	Notes Limitations identified by author: • Some concern about the validity of children's self- reports • Possibility of children not remembering if precautions were taken (often parent decision) • Clustering was not accounted for in the analysis • Only 62% of parents and their children agreed to participate (slightly lower participation in control group; unclear if
grades four, five and six" Study design: RCT	health clerk in residence." Selected population: four schools agreed to participate: consent	validity, including history, maturation, testing, statistical regression, and instrumentation"	responses summed into a measure of knowledge); o <u>Attitudes:</u> 11	<ul> <li>Not pre-tested – immediate: 9.76 intervention (66 participants); 6.56 control (52 participants); p not reported</li> <li>Not pre-tested – delayed (#): 8.60</li> </ul>	<ul> <li>participants knew</li> <li>which group they</li> <li>would be</li> <li>allocated to)</li> <li>Adjustment for</li> </ul>
Internal validity <sup>§</sup> : -	participate; consent forms were distributed to all 723 students and their parents – 447 students and their parents gave consent (251 in intervention and	Intervention/s "The "Sunny Days, Healthy Ways" curriculum consisted of five multidisciplinary units and a student workbook that presented material from	"yes/no" items; two subscales were identified – favour a tan (3 items) and barriers to sunscreen use (2	<ul> <li>intervention (68 participants); 6.88 control (40 participants); p=0.005</li> <li>Knowledge score</li> <li>28.82 intervention (102 participants); 18.74 control (75 participants); p reported as 0.000</li> </ul>	baseline might limit direct applicability Limitations identified by review team:

Study Population and details setting	Method of allocation to intervention/control	Outcomes and methods of analysis	Results	Notes
validity <sup>†</sup> : 3196 in control group)Age: not reported (children in grades four to six)Female: 49.4% intervention group; 48.5% control group; Race/ethnicity: White: 65.7% intervention; 61.7% control Black: 2.0% intervention; 3.6% control Hispanic: 13.1% intervention; 7.7% control Other: 15.5% intervention; 15.8% control Unknown: 3.6% intervention; 11.2% controlSocioeconomic status: (annual income) not reportedExcluded population: not reportedExcluded population: not reported	<ul> <li>science, history, social studies, health, and geography in a comprehensive cause-and-consequence presentation about the relationship between human beings and the sun. The units cover properties of the sun, composition of human skin, historic attitudes toward tanning, skin cancer, and strategies to reduce sun exposure in an interactive lesson/activity format. Each unit (about 50 minutes in length) contained lesson material, in-class and take-home activities, a glossary of key terms, a quick review, and a student/parent newsletter.</li> <li>Health communication experts, dermatologists, teachers, and curriculum consultants collaborated to develop the curriculum. It complements state and national skin cancer prevention information resources (), although most preexisting programs are aimed at children in kindergarten through third grade. The curriculum also conformed to the</li> </ul>	items); higher scores indicated less sun protective attitudes; Preventive behaviour (child): 13 items measuring frequency of practicing preventive behaviours ("always/sometim es/never"); three subscales were identified – sunscreen use in summer (2 items), lip balm use (2 items), hat use (2 items); remaining items measured <i>"use of protective clothing in summer and winter, sunscreen in winter, sunglasses on sunny days, frequency of lying out in the sun to get a tan, the SPF of sunscreen used, and parts of the body on which sunscreen</i>	AttitudeFavour a tan•0.98 intervention (90 participants); 1.34 control (63 participants); p=0.012•Immediate: 1.19 intervention (38 participants); 1.11 control (39 participants); p not reported•Delayed: 0.77 intervention (52 participants); 1.58 control (24 participants); p=0.002Barriers to sunscreen use•0.27 intervention (99 participants); 0.47 control (73 participants); p=0.017•Immediate: 0.33 intervention (42 participants); 0.37 control (44 participants); p not reported•Delayed: 0.21 intervention (57 participants); 0.57 control (29 participants); p=0.057Student's behaviour Entire scale•1.95 intervention (102 participants); p=0.512Sunscreen use in summer•(#) 2.25 intervention (232 participants); 2.21 control (169 participants); p=0.592•Pre-tested: 2.12 intervention (104	<ul> <li>Given the time in which the study was conducted, it could not possibly have measured actual behaviours in relation to winter</li> <li>Relatively short follow-up</li> <li>Not ITT</li> <li>Often unclear to which groups and follow-up periods results referred</li> <li>Scales for outcomes unclear</li> <li>No indication what is a meaningful difference for most outcomes</li> <li>Evidence gaps and/or recommendations for future research:</li> <li>Incorporation of messages from peers to enhance credibility</li> <li>Increase of parental involvement</li> </ul>

Study details	Population and setting	Method of allocation to intervention/control	Outcomes and methods of analysis	Results	Notes
		intervention/controldisease prevention section of the State of Arizona Board of Education's 	<ul> <li><i>is applied"</i>; higher scores indicated more frequent use of each behaviour;</li> <li><u>Parent's frequency of practicing sun protective behaviour</u>: 8 items ("always/sometim es/never")</li> <li><u>Skin sun sensitivity</u>: combination of hair, eye and skin colour with skin's reaction to 15 minutes of unprotected sun exposure in the summer (score ranged from 4 to 18 with higher score indicating more sensitivity)</li> <li><u>Ethnicity</u></li> <li><u>Sex</u></li> <li><u>Years lived in Arizona</u></li> </ul>	<ul> <li>participants); 2.21 control (78 participants); p not reported</li> <li>Not pre-tested (#): 2.36 intervention (128 participants); 2.21 control (91 participants); p=0.042</li> <li>Lip balm use</li> <li>1.78 intervention (99 participants); 1.68 control (70 participants); p=0.213</li> <li>Hat use</li> <li>1.93 intervention (102 participants); 1.90 control (75 participants); p=0.673</li> <li>Wear protective clothing in summer</li> <li>1.51 intervention (99 participants); 1.44 control (72 participants); p=0.425</li> <li>Wear protective clothing in winter</li> <li>2.02 intervention (239 participants); 1.94 control (177 participants); p=0.263</li> <li>Immediate: 1.95 intervention (112 participants); 2.01 control (104 participants); p not reported</li> <li>Delayed: 2.09 intervention (127 participants); 1.84 control (73 participants); p=0.019</li> <li>Sunscreen use in winter</li> <li>1.39 intervention (99 participants); 1.30 control (75 participants); p=0.241</li> </ul>	Notes Source of funding: Supported by a grant from the Arizona Disease Control Research Commission and the National Cancer Institute
		group design"	two out of three scales:	Wear sunglasses on sunny days o 1.83 intervention (102	

Study details	Population and setting	Method of allocation to intervention/control	Outcomes and methods of analysis	Results	Notes
		Sample sizes: Total n = 447 Intervention n = 251 Control n = 196 Baseline comparisons: "No significant differences were found between students in the curriculum groups and control groups with respect to grade level, sex, sthnic background, or skin sun sensitivity." Study sufficiently powered?: not reported	<ul> <li>a* scale – hue; was not used (only shows skin erythema – within 48 to 72 hours after sun exposure)</li> <li>L* scale – lightness; decrease in score indicates skin darkening;</li> <li>b* scale – saturation; increase in score indicates skin darkening;</li> <li>b* scale – saturation; increase in score indicates skin darkening;</li> <li><i>To reduce variation in</i> readings, five measures were made on the underside of each student's upper arm (an unexposed area) and five measures were made on the lower outer side of the same arm (an exposed area). Readings were averaged at each measurement site for analysis."</li> </ul>	<ul> <li>participants); 1.78 control (75 participants); p=0.521</li> <li>Immediate: 1.82 intervention (44 participants); p not reported</li> <li>Delayed: 1.84 intervention (58 participants); p=0.033</li> <li>Play outside early or late in the day</li> <li>1.78 intervention (100 participants); 1.90 control (73 participants); p=0.274</li> <li>Try not to get sunburned</li> <li>2.60 intervention (101 participants); p=0.125</li> <li>Lie out in the sun to get a tan</li> <li>2.60 intervention (102 participants); p=0.112</li> <li>Immediate: 2.49 intervention (44 participants); p=0.112</li> <li>Immediate: 2.49 intervention (44 participants); p=0.005</li> <li>SPF of sunscreen</li> <li>(#) 2.92 intervention (195 participants); p=0.003</li> <li>Pre-tested: 2.85 intervention (82 participants); p=0.003</li> <li>Pre-tested: 2.85 intervention (49 participants); p=0.003</li> <li>Not pre-tested (#): 2.96</li> </ul>	

Study details	Population and setting	Method of allocation to intervention/control	Outcomes and methods of analysis	Results	Notes
			Secondary outcomes: not reported	intervention (113 participants); 2.67 control (57 participants); p reported as 0.000	
				Where to apply sunscreen	
			Follow-up periods:	o 2.41 intervention (100	
			Pre-tested groups completed the survey <i>"just before the</i>	participants); 2.48 control (71 participants); p=0.490	
			implementation of the curriculum".	<u>Parent's behaviour</u> Entire scale	
			"Baseline skin tanning measurements were performed () at the beginning of the	<ul> <li>1.85 intervention (102 participants); 1.85 control (75 participants); p=0.965</li> </ul>	
			intervention in the	Frequency check child's skin	
			pretested groups"	<ul> <li>0.97 intervention (98 participants);</li> <li>0.65 control (68 participants);</li> <li>p=0.032</li> </ul>	
			"The immediate posttest groups completed the ()	What to do if change found in child's skin	
			survey 1 week after completing the curriculum, in early April. The delayed posttest groups completed the survey	<ul> <li>2.46 intervention (91 participants);</li> <li>2.11 control (62 participants); p reported as 0.000</li> </ul>	
			8 weeks after	Chroma meter scores	
			implementation in mid-May. Skin tanning	L* score	
			measurements also were obtained for the delayed posttest	<ul> <li>Upper arm: 65.65 intervention (58 participants); 64.94 control (33 participants); p=0.045</li> </ul>	
			groups at this time."	<ul> <li>Lower arm: 54.49 intervention (58 participants); 53.11 control (33 participants); p=0.009</li> </ul>	
			Method of analysis: Not ITT	<ul> <li>Difference (#): 10.49 intervention (128 participants); 11.72 control</li> </ul>	

Study details	Population and setting	Method of allocation to intervention/control	Outcomes and methods of analysis	Results	Notes
			2 (curriculum vs. no curriculum) x 2 (pretested vs. not pretested) x 2 (immediate vs. delayed) ANOVA to determine the effect of pretesting. <i>"If the main</i> <i>effect of pretesting or</i> <i>its interaction with the</i> <i>curriculum was</i> <i>significant, then the</i> <i>main effect of</i> <i>pretesting and its</i> <i>interaction with the</i> <i>curriculum and the</i> <i>interaction between</i> <i>intervention and time</i> <i>of posttesting tested</i> <i>the persistence of the</i> <i>effects of the</i> <i>curriculum."</i> If the main effect of pre- testing and its <i>interaction with the</i> <i>curriculum."</i> If the main effect of pre- test groups were dropped from the analysis and a 2 (curriculum vs. no curriculum) x 2 (immediate vs. delayed) ANCOVA with the pre-test score as a covariate was used.	<ul> <li>(88 participants); p=0.003</li> <li>b* score</li> <li>Upper arm: 13.01 intervention (58 participants); 13.02 control (33 participants); p=0.975</li> <li>Lower arm: 19.56 intervention (58 participants); 19.25 control (33 participants); p=0.293</li> <li>Difference: -6.64 intervention (58 participants); of 08 control (33 participants); p=0.211</li> <li>REPLICATION STUDY</li> <li>Mean post-test scores adjusted for pre-test scores.</li> <li><u>Knowledge</u></li> <li>Term recognition: 9.74 intervention (46 participants); p reported as 0.000</li> <li>Knowledge: 30.49 intervention (46 participants); p reported as 0.000</li> <li>Knowledge: 30.49 intervention (46 participants); p reported as 0.000</li> <li>Knowledge: 30.49 intervention (46 participants); p reported as 0.000</li> <li>Knowledge: 30.49 intervention (46 participants); p reported as 0.000</li> <li>Knowledge: 30.49 intervention (46 participants); p reported as 0.000</li> <li>Knowledge: 30.49 intervention (46 participants); p reported as 0.000</li> <li>Knowledge: 30.49 intervention (46 participants); p reported as 0.000</li> <li>Knowledge: 30.49 intervention (46 participants); p reported as 0.000</li> <li>Knowledge: 30.49 intervention (46 participants); p reported as 0.000</li> <li>Knowledge: 30.49 intervention (46 participants); p reported as 0.000</li> </ul>	

Study details	Population and setting	Method of allocation to intervention/control	Outcomes and methods of analysis	Results	Notes
			Analyses for chroma meter scores omitted the immediate/delayed factor, as all measurements were carried out in mid May. The replication study used a one-way (intervention vs. control) ANCOVA with pre-test as covariate. Pre-test skin tanning readings were unavailable and therefore omitted from the analysis.	<ul> <li>control (50 participants); p=0.686</li> <li><u>Student's behaviour</u></li> <li>Entire scale: 2.04 intervention (46 participants); 2.00 control (50 participants); p=0.402</li> <li>Sunscreen use in summer: 2.40 intervention (46 participants); p=0.008</li> <li>Lip balm use: 1.80 intervention (45 participants); p=0.008</li> <li>Lip balm use: 1.80 intervention (45 participants); 1.92 control (46 participants); p=0.222</li> <li>Hat use: 1.91 intervention (46 participants); p=0.605</li> <li>Wear protective clothing in summer: 1.55 intervention (44 participants); p=0.605</li> <li>Wear protective clothing in summer: 1.59 control (50 participants); p=0.712</li> <li>Wear protective clothing in winter: 2.14 intervention (46 participants); 1.93 control (50 participants); p=0.053</li> <li>Sunscreen use in winter: 1.51 intervention (46 participants); 1.93 control (51 participants); p=0.523</li> <li>Play outside early or late in the day: 1.86 intervention (46 participants); 1.92 control (50 participants); p=0.523</li> <li>Play outside early or late in the day: 1.86 intervention (46 participants); 1.92 control (50 participants); p=0.523</li> <li>Play outside early or late in the day: 1.86 intervention (46 participants); 1.92 control (50 participants); p=0.523</li> <li>Play outside early or late in the day: 1.86 intervention (46 participants); 1.92 control (50 participants); p=0.617</li> <li>Try not to get sunburned: 2.76</li> </ul>	

Study details	Population and setting	Method of allocation to intervention/control	Outcomes and methods of analysis	Results	Notes
				intervention (46 participants); 2.61 control (51 participants); p=0.142	
				<ul> <li>Lie out in the sun to get a tan: 2.49 intervention (45 participants); 2.32 control (51 participants); p=0.115</li> </ul>	
				<ul> <li>SPF of sunscreen: 2.92 intervention (24 participants); 2.84 control (27 participants); p=0.356</li> </ul>	
				<ul> <li>Where to apply sunscreen: 2.59 intervention (46 participants); 2.48 control (49 participants); p=0.328</li> </ul>	
				Parent's behaviour	
				<ul> <li>Entire scale: 1.99 intervention (45 participants); 1.94 control (51 participants); p=0.400</li> </ul>	
				<ul> <li>Frequency check child's skin: 0.88 intervention (45 participants); 1.10 control (48 participants); p=0.310</li> </ul>	
				<ul> <li>What to do if change found in child's skin: 2.19 intervention (43 participants); 2.14 control (49 participants); p=0.654</li> </ul>	
				Results stratified by grade level were not extracted, as this was apparently not a pre-specified analysis.	
				Secondary outcomes: N/A	
				Attrition details:	

Study details	Population and setting	Method of allocation to intervention/control	Outcomes and methods of analysis	Results	Notes
				"Sixteen consenting students who were scheduled to complete both a pretest and a posttest did not complete both tests" – no indication which groups they were allocated to	
				Outcomes reported for differing numbers of participants.	

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- I. One-to-one or group-based verbal advice (with or without use of information resources).
- II. Mass-media campaigns.
- III. Leaflets, other information or teaching resources or printed material including posters.
- IV. New media: the Internet (including social networking sites), emedia and text messaging.

§ The internal validity score of a study may vary depending on the reliability and validity of the outcome measures of interest, score ++ if the quality assessment score is greater than or equal to 60% and less than or equal to 80%, and score - if the quality assessment score is less than 60%.

†

- 1. Likely to be applicable across a broad range of populations and settings.
- 2. Likely to be applicable across a broad range of populations and settings, assuming it is appropriately adapted.
- 3. Applicable only to populations or settings included in the studies the success of broader application is uncertain.
- 4. Applicable only to settings or populations included in the studies.

## Table 4 Quality assessment: Buller 1996

Study	Appropriate and clearly focused question	Randomised assignment	An adequate concealment method	Blind subjects and investigators about intervention allocation.	Groups are similar at baseline	The only difference between groups is the intervention	All relevant outcomes are measured in a standard, valid and reliable way.	Drop out rate less than 20% in every group?	Intention- to-treat analysis	Where the study is carried out at more than one site, results are comparable for all sites.	Total no. Y (%)	Quality rating <sup>§</sup>
Buller 1996 <sup>1</sup>	Y	Y	СТ	СТ	СТ	N	Y	Y	N	СТ	4 (50%)	-
CT: canr § The int	ernal validity sc			ig on the reliabilit								

than 60%.

# Vitols<sup>3</sup> - *cluster (unclear: school or class) controlled before and after study*

This controlled before and after study (rated -) was set in Sydney, Australia. Study year was not reported. Of 1040 children who participated in the pre-test, 983 were post-tested and data from only those who participated in both tests was analysed. No information was provided on numbers of participants allocated to study arms.

Age was reported as ranging between eight and 12 years. 37% of children were female. No further demographic characteristics were reported and no baseline comparisons were made.

This study compared two types of intervention format: didactic (lecture) and interactive (question and answer session).

The intervention covered "the functions of the skin, the fact that sunburn, specifically from ultraviolet rays can lead to skin cancer; ways to protect oneself from the sun (students were shown shirts, hats and sunglasses and told about sunblock creams and to stay in the shade, especially between 11 a.m. and 3 p.m.); the facts that sunburn can also occur on cloudy days, when swimming outdoors and when in the snow, and that the most important time of life to protect oneself from the sun is as a child. Each student was then given a sticker and colouring sheet, which has messages reinforcing ways to protect oneself from the sun."

"The interactive session conveyed the same information as the lecture, except that there was student involvement. The students participated in a question-andanswer session, with the questions covering the same areas as the didactic lecture. The correct answers provided by the students, and any information forgotten by them, were summarised at the end of the session." An 18-item questionnaire designed to test *"knowledge about sunburn, skin cancer and its causes, sun-protection mechanisms and attitudes and intentions to protective behaviour"* was used. It contained true/false items, multiple choice questions and open-ended questions. No further information was provided on methods of outcome assessment. The questionnaire was distributed during class time. The baseline assessment was carried out immediately before the intervention and the follow-up assessment two weeks later.

#### Results

Results were mainly reported as in a before and after study without comparison between groups. This information was not extracted, as before and after studies were not analysed in this report.

#### Primary outcomes

The only information relevant to the controlled before and after study design provided was: "Both the formal presentation and the interactive session were effective in increasing knowledge (P<0.0005 for both groups), with no significant differences in the average gain in scores between these two teaching methods."

#### Secondary outcomes

No results for secondary outcomes of this report were provided.

#### Limitations

Internal validity was rated "-". Full details of quality assessment are reported in Table 6.

The findings are probably applicable only to settings or populations included in the study.

Authors highlighted that children already had a high baseline knowledge level. It is also possible that participants did not report their actual intentions to protect themselves from the sun, but rather tried to give answers that they thought they were expected to give.

Other limitations were identified when conducting this review. This study did not provide sufficient information on the population, intervention, methods of allocation to groups, and the unit of cluster allocation was not clear. Although it was designed as a controlled before and after study, results were reported mainly for both intervention groups together, comparing baseline with follow-up. No information was provided if clustering was taken into account in the analysis. Follow-up was relatively short.

#### Evidence statement

An Australian cluster controlled before and after study (rated -) in 983 children aged eight to 12 years aimed to compare the effectiveness of two formats of teaching: a presentation and a question and answer session. Both sessions covered "the functions of the skin, the fact that sunburn, specifically from ultraviolet rays can lead to skin cancer; ways to protect oneself from the sun (students were shown shirts, hats and sunglasses and told about sunblock creams and to stay in the shade, especially between 11 a.m. and 3 p.m.); the facts that sunburn can also occur on cloudy days, when swimming outdoors and when in the snow, and that the most important time of life to protect oneself from the sun is as a child. Each student was then given a sticker and colouring sheet, which has messages reinforcing ways to protect oneself from the sun."

Results were presented mainly combining data for both teaching formats and comparing baseline with follow-up assessments, rather than comparing formats. For the latter it was only stated, that *"both the formal presentation and the interactive session were effective in increasing knowledge (P<0.0005 for both* 

groups), with no significant differences in the average gain in scores between these two teaching methods."

The findings are probably applicable only to settings or populations included in the study. (Vitols $^{3}$ )

### Table 5 Evidence table: Vitols

Study details	Population and setting	Method of allocation to intervention/control	Outcomes and methods of analysis	Results	Notes
Authors: Vitols et al. <sup>3</sup>	Source population/s: not reported	Method of allocation: not reported	Primary Outcomes: 18-item questionnaire designed to test	Primary outcomes: Results were reported as in a before and after study (not extracted into this	Limitations identified by author:
Year: 1997 Aim of	<b>Country:</b> Australia <b>Study year:</b> not reported	Measures to minimise confounding: not reported	"knowledge about sunburn, skin cancer and its causes, sun- protection	table) without comparison between groups. The only information relevant to controlled before and after study design was:	relatively high baseline knowledge level
study: "1. to assess the level of knowledge primary school children have about sunburn, skin cancer and protective behaviour; 2.	Eligible population: not reported Selected population: "A convenience sample of three state and two private schools from Sydney's northern districts and one private boys' school from	Intervention/s Two types of intervention format were compared: didactic (lecture) and interactive. The intervention covered "the functions of the skin, the fact that sunburn, specifically from ultraviolet	mechanisms and attitudes and intentions to protective behaviour." Knowledge was tested at baseline in a questionnaire distributed during class time. It contained true/false	"Both the formal presentation and the interactive session were effective in increasing knowledge (P<0.0005 for both groups), with no significant differences in the average gain in scores between these two teaching methods." Secondary outcomes: N/A Attrition details: 1040 children	<ul> <li>It is possible that children did not report their actual intentions to protect themselves from the sun, but rather tried to give the answers that they thought they were expected to give</li> </ul>
to assess their intention towards	Sydney's inner west." Permission to test students was obtained	rays can lead to skin cancer; ways to protect oneself from the sun	items, multiple choice questions and open- ended questions.	completed the pre-test and 983 (94.5%) the post-test	Limitations identified by review team:
future personal protective behaviour; 3. to determine	from school principals. "All students in Years 3 to 6 (aged 8 to 12 years) participated in the survey, a total of	(students were shown shirts, hats and sunglasses and told about sunblock creams and to stay in the shade,	Adverse events: not reported		<ul> <li>Results reported as in a before and after study, not a controlled before and after</li> </ul>
by a pretest and post-test procedure the degree to	1040 children." Age: 8 to 12 years	especially between 11 a.m. and 3 p.m.); the facts that sunburn can also occur on cloudy days,	Secondary outcomes: not reported		<ul> <li>Poor reporting</li> <li>Relatively short follow-up</li> </ul>
which information given to them	Female: 37% Race/ethnicity: not reported	when swimming outdoors and when in the snow, and that the most	Follow-up periods: Baseline		• Unit of cluster allocation unclear
in this area improved	Γεροιίεα	important time of life to protect oneself from the	questionnaire immediately before		<ul> <li>Not reported if clustering taken</li> </ul>

Study details	Population and setting	Method of allocation to intervention/control	Outcomes and methods of analysis	Results	Notes
their level of knowledge and was	Socioeconomic status: (annual income) not reported	sun is as a child. Each student was then given a sticker and colouring	the intervention and follow-up questionnaire two		into account in data analysis
retained; and 4. to compare the	Excluded population: not reported	sheet, which has messages reinforcing ways to protect oneself	weeks later; Method of analysis:		Evidence gaps and/or recommendations
effectiveness of a formal lecture with	Setting: school	from the sun." "The interactive session conveyed the same	Numbers of correct answers in knowledge		for future research: Not reported
an interactive sessionin teaching about sun protection."		information as the lecture, except that there was student involvement. The students participated in a question-and-answer session, with the	test were compared in pre-test and post-test with the chi-squared test of significant differences;		Source of funding: not reported
Study design: controlled before and after		questions covering the same areas as the didactic lecture. The correct answers provided by the students, and any information forgotten by them, were summarised at	Data only from children who completed both baseline and follow-up test was used;		
Internal validity <sup>§</sup> : -		the end of the session."			
External validity <sup>†</sup> : 4		Intervention category <sup>*</sup> : I			
		Intervention period: 30- 45 minutes			
		<b>Comparator/s:</b> interventions compared with each other			
		Sample sizes (without mixed intervention arm):			
		<b>Total n =</b> 1040 (983			

Study details	Population and setting			Results	Notes
		analysed)			
		Intervention (didactic) n = not reported			
		Intervention (interactive) n = not reported			
		Baseline comparisons: not reported			
		Study sufficiently powered?: power calculation not reported			

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- I. One-to-one or group-based verbal advice (with or without use of information resources).
- II. Mass-media campaigns.
- III. Leaflets, other information or teaching resources or printed material including posters.
- IV. New media: the Internet (including social networking sites), emedia and text messaging.

§ The internal validity score of a study may vary depending on the reliability and validity of the outcome measures of interest, score ++ if the quality assessment score is greater than or equal to 60% and less than or equal to 80%, and score - if the quality assessment score is less than 60%.

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- 4. Applicable only to settings or populations included in the studies.

## Table 6 Quality assessment: Vitols

Study	Contemporaneou s data collection	Appropriate choice of control site (if 2 <sup>nd</sup> site used)	Similarit y of baseline measure s	Similarity of study/ control providers	Blinded outcome assessmen t	Protection against contaminatio n	Reliabilit y of outcome measure s	Follow-up of individual s	Total no. Y (%)	Qualit y rating §
Vitols <sup>3</sup>	Y	Y	СТ	СТ	CT	СТ	CT	Υ	3 (38)	-
Y: yes N: no CT: cannot NA: not app										
	al validity score of a stuater than 80%, score + i									

assessment score is less than 60%.

#### References

- 1 Buller DB, Buller MK, Beach B, Ertl G. Sunny days, healthy ways: Evaluation of a skin cancer prevention curriculum for elementary school-aged children. *Journal of the American Academy of Dermatology* 1996; **35**(6):911-922.
- 2 Structure of US Education Sysytem and Age Pattern. Access date: 6 Jan. 2009,
- 3 Vitols P, Oates RK. Teaching children about skin cancer prevention: Why wait for adolescence? *Australian and New Zealand Journal of Public Health* 1997; **21**(6):602-605.